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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) 001227/0152
<p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]</p> <p>on _____</p> <p>Signature _____</p> <p>Typed or printed name _____</p>		<p>Application Number 10/509,075</p> <p>Filed 09/22/2004</p> <p>First Named Inventor Raoul Donath</p> <p>Art Unit 3733</p> <p>Examiner Woodall, Nicholas W.</p>
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p>		
<p>I am the</p> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>35,340</u>.</p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p> <p><u>/Giuseppe Molaro/</u> Signature Giuseppe Molaro(52,039) for Mr Rothery Typed or printed name</p> <p><u>212-806-6114</u> Telephone number</p> <p><u>October 29, 2008</u> Date</p>		
<p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p> <p><input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.</p>		

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**APPLICANT'S REMARKS ACCOMPANYING
THE PRE-APPEAL BRIEF REQUEST FOR REVIEW**

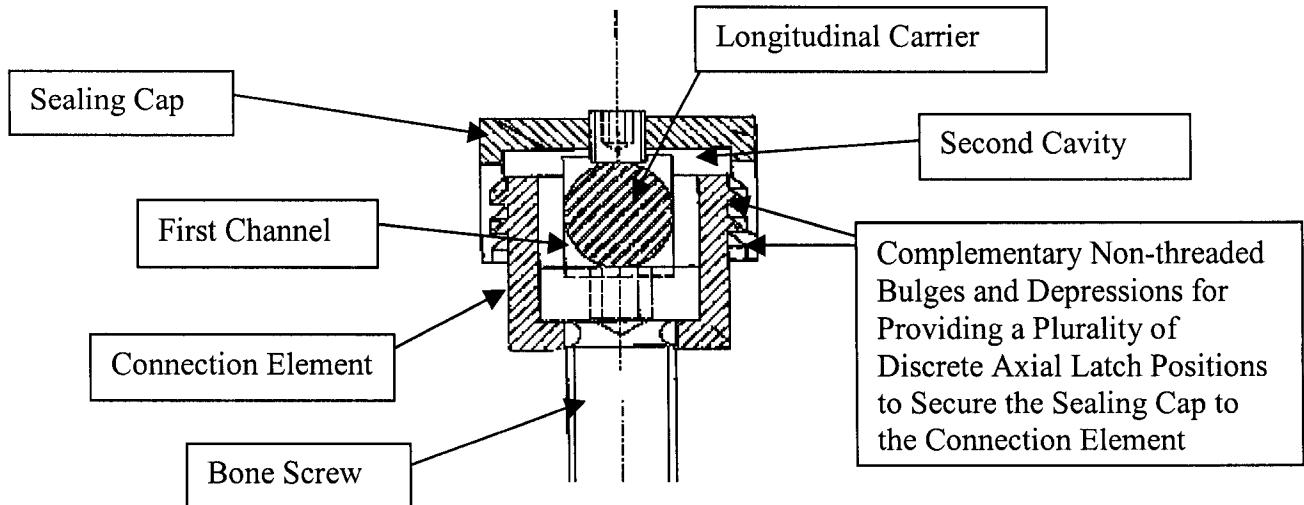
In accordance with the *New Pre-Appeal Brief Conference Pilot Program*, Applicant hereby submits a Pre-Appeal Brief and a Pre-Appeal Brief Request for Review. The Pre-Appeal Brief and Pre-Appeal Brief Request for Review are being filed with a timely filed Notice of Appeal. Applicant respectfully submits that the claims have been twice rejected and are currently under Final Rejection, and, therefore, a Notice of Appeal is proper in accordance with 35 U.S.C. §134(a). Applicant respectfully requests detailed review of the rejections described herein, which Applicant respectfully submits are overcome by the below-listed arguments.

1. The Examiner's Rejection of Independent Claim 1 and Dependent Claims 2, 4, 5, 9, 10 and 18
under 35 U.S.C. §103(a)

The Examiner rejected claims 1, 2, 4, 5, 9 and 18 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,755,829 to Bono ("Bono") in view of U.S. Published Patent Application No. 2001/0012937 to Schaffler-Wachter ("Schaffler-Wachter") and U.S. Patent No. 5,989,254 to Katz ("Katz"). In addition, the Examiner rejected claims 1, 2, 4, 5, 10 and 18 under 35 U.S.C. §103(a) as being unpatentable over Bono in view of Schaffler-Wachter and U.S. Patent No. 6,090,111 to Nichols ("Nichols").

Independent claim 1 is directed a device for connecting a longitudinal carrier to a bone screw and recites, *inter alia*, a connection element and a sealing cap. As representatively shown in the attached figure, the connection element includes a central axis, an external surface and a first channel passing through the connection element for receiving a longitudinal carrier. The sealing cap includes a second cavity opening at a front end thereof for receiving the connection element, the second cavity including an internal surface. *The external surface of the connection element and the internal surface of the second cavity formed in the sealing cap include complementary non-threaded bulges and depressions*

for securing the sealing cap to the connection element, the bulges and depressions providing a plurality of discrete axial latch positions parallel to the central axis, each successive latch position axially displacing the sealing cap over the connection element...¹



Bono discloses a pedicle screw assembly 31 including a top member 33. The top member 33 includes a rod receiving channel 34 for receiving a spinal rod and contains, at its uppermost region 35, a plurality of partial flange members 36a, 36b, 36c, 36d which extend radially outward from the perimeter of the uppermost region 35 and have respective spaces 37a, 37b therebetween. The pedicle screw assembly 31 further includes a closure cap 40 that is sized and configured to fit over and around the upper portion 35 of the rod receiving top member 33. That is, the cap 40 includes a body 41 having a pair of dependent side members 43a, 43b, each of the side members 43a, 43b having mating inwardly directed protrusions 46a, 46b, and 46c, 46d, respectively, which are spaced apart and positioned to correspond to the partial flange members 36a-36d formed on the top member 33. In use, the protrusions

¹ Independent claim 1 further recites, *inter alia*, a securing element for engaging a head of a bone screw to prevent the bone screw from passing through an upper end of the connection element prior to attachment of the sealing cap to the connection element. The examiner relies (i) upon Katz for disclosing the securing element wherein the securing element is a pin sized and configured to be pressed into a hole formed in the connection element, and (2) upon Nichols for disclosing the securing element wherein the securing element is a snap ring. Only for purposes of this Pre-Appeal Brief, the combination of Katz and/or Nichols for disclosure of a securing element is not challenged.

46a, 46b, 46c, 46d formed on the closure cap 40 are aligned with and pushed through the spaces 37a, 37b formed in between the plurality of partial flange members 36a, 36b, 36c, 36d and then rotated via partial rotation of the closure cap 40 into engagement with the partial flange members 36a, 36b, 36c, 36d in the manner of a bayonet style closure cap as is generally known in the art.

As admitted by the Examiner, Bono fails to disclose a device wherein the complementary arresting means includes non-threaded bulges and depressions providing a plurality of latch positions wherein each latch position axially displaces the sealing cap of the connection element. Rather, the Examiner relies upon Schaffler-Wachter for such disclosure.

Schaffler-Wachter discloses a pedicle screw assembly comprising a screw 1 and a cap 5, the cap 5 being formed by an inner part 6 and an outer part 7. The inner part 6 including a partially spherical cavity 24 for receiving the spherical head of the screw 1 and an upwardly cylindrical recess 14 for receiving a spinal rod 2. The outer part 7 is a U-shaped member having a downwardly facing partially spherical seat 16 for receiving the rod 2. The outer part 7 includes a pair of arms 9 having hooks 10 formed on an end thereof for engaging the under edges of the inner part 6.

2. The Examiner Omits One or More Essential Elements Needed for A Prima Facie Rejection

As admitted by the Examiner, the combination of Bono and Schaffler-Wachter fails to disclose a connection element and a sealing cap including *complementary non-threaded bulges and depressions such that the bulges and depressions provide a plurality of discrete axial latch positions so that each successive latch position axially displaces the sealing cap over the connection element*. Rather, according to the Examiner, it would have been obvious to modify Bono with Schaffler-Wachter to further incorporate a plurality of bulges and depressions to provide a plurality of discrete axial latch positions so that each successive latch position axially displaces the sealing cap over the connection element.

It is respectfully submitted that the Examiner has failed to demonstrate each and every limitation in the prior art.² Instead, the Examiner conclusory states that it would have been obvious to one of ordinary skill in the art to incorporate a plurality of bulges and depressions to provide a plurality of discrete axial latch positions so that each successive latch position axially displaces the sealing cap over the connection element even though such limitation is not found in the prior art since, according to the Examiner, it only requires a “mere duplication of essential working parts.”

It is respectfully submitted that the Examiner has failed to fulfill the requirements for supporting an obviousness rejection and hence has failed to establish a *prima facie* rejection. *See MPEP 2141 citing KSR*, 82 USPQ2d at 1396 (rejections on obviousness cannot be sustained by merely conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness). It is respectfully submitted that the Examiner has not articulated a reason why the claimed invention would have been obvious. Instead, Applicant respectfully submits that the Examiner relies on impermissible hindsight reconstruction in claiming that the proposed modification would have been obvious, without providing supporting evidence and without demonstrating each and every claim limitation in the cited prior art.

Accordingly, at least for the reasons set forth above, Applicant respectfully submits that the Examiner’s rejection of independent claim 1 and dependent claims 2, 4, 5, 9, 10 and 18 are erroneous and respectfully requests withdrawal thereof. Favorable consideration and prompt allowance of independent claim 1 is respectfully requested.

² In fact, in his pursuit to locate each and every limitation in the prior art, the Examiner previously relied upon a seal tight soup container (U.S.P.N. 5,395,003 to Matsuda) for disclosure of a plurality of bulges and depressions to provide a plurality of discrete axial latch positions so that each successive latch position axially displaces the sealing cap over the connection element to reject the pending claims. Based on a telephonic Examiner Interview and Applicant’s Amendment dated April 14, 2008, Applicant demonstrated that Matsuda did not disclose, teach or suggest this required element of the claim. In response the Examiner has withdrawn his reliance on Matsuda.

3. The Examiner's Rejection of Independent Claims 19 and 21, and Dependent Claims 15, 16, 17 and 20 under 35 U.S.C. §103(a)

The Examiner rejected independent claims 19 and 21, and dependent claims 15 and 20, under 35 U.S.C. §103(a) as being unpatentable over Bono in view of Schaffler-Wachter. In addition, the Examiner rejected dependent claims 16 and 17 under 35 U.S.C. §103(a) as being unpatentable over Bono in view of Schaffler-Wachter in further view of Katz.

Independent claims 19 and 21 recite features of the device for connecting a longitudinal carrier to a bone screw including the complementary non-threaded bulges and depressions for securing the sealing cap to the connection element wherein the bulges and depressions provide a plurality of discrete axial latch positions parallel to the central axis so that each successive latch position axially displaces the sealing cap over the connection element. Accordingly, for reasons described above, it is respectfully submitted that the cited prior art does not disclose, teach, suggest or render obvious all of the limitations of independent claims 19 and 21. Favorable consideration and prompt allowance of independent claims 19 and 21, and dependent claims 15, 16, 17 and 20, is respectfully requested.

In the event that there are any questions, or should additional information be required, please contact Applicant's attorney at the number listed below.

Respectfully submitted,

Date: October 29, 2008

/Giuseppe Molaro/
Giuseppe Molaro (Reg. No. 52,039)

For: Brian M. Rothery
Registration No. 35,340

Attorney for Applicants
Stroock & Stroock & Lavan, LLP